

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

PENNSYLVANIA EMPLOYEE BENEFIT  
TRUST FUND, on behalf of itself and all others  
similarly situated,

Plaintiffs,

v.

ZENECA, INC. and ASTRAZENECA  
PHARMACEUTICALS, L.P.,

Defendants.

No. 05-075-SLR

**PLAINTIFFS' MOTION FOR JUDICIAL NOTICE OF FDA RULINGS**

Plaintiffs respectfully move that the Court take judicial notice of the documents appended hereto.

In the September 9, 2005 hearing on Defendants' motion to dismiss the complaint, Defendants argued that the Food and Drug Administration ("FDA") approved Nexium as superior to Prilosec. Specifically, Defendants argued:

. . . By approving a 40-milligram dose of Nexium for healing erosive esophagitis, the FDA relied upon and necessarily found that the studies that plaintiffs want to say are skewed and slanted in their words are, in fact, adequate and well controlled studies to the point that the FDA approved summaries of these studies on the label that appears necessarily by law covers every prescription of

Nexium, and the FDA approved in particular the 40-milligram dose in comparison to both 20-milligram doses of Nexium and 20-milligram doses of Prilosec, 20 milligrams of Prilosec being the maximum recommended dose for the same indication of healing erosive esophagitis.

And when one looks at the labeling of Prilosec, one sees that not only is 20 milligrams the maximum dose of Prilosec, but the FDA declined to recommend a 40-milligram dose of Prilosec.

*Hearing transcript, Lines 3-19, pg. 10 (D.I. #47 - Exhibit A attached hereto).*

So what plaintiffs want to call a game is, in fact, the FDA's decision to recognize that Nexium at 40 milligrams is more effective at healing erosions in the esophagus and at producing sustained resolution of heartburn symptoms for patients with erosive esophagitis than Prilosec at its maximum dose of 20 milligrams.

*Hearing transcript, Lines 19-24, pg. 13 (D.I. #47 - Exhibit A attached hereto).*

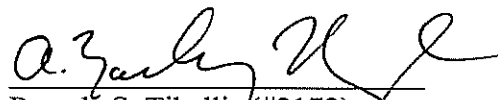
Plaintiffs respectfully request that the Court take judicial notice of the additional documents appended hereto. Plaintiffs' exhibits are actual documents from the FDA record that refute Defendants' assertions the FDA approved Nexium as superior to Prilosec. These documents consist of the following:

<b><u>EXHIBIT</u></b>	<b><u>TAB</u></b>
NDA: 21-153, Clinical Pharmacology with Biopharmaceuticals Review, September 18, 2000.	B
NDA: 21-153, Medical Officer's Review, September 21, 2000.	C
NDA: 21-153, Approvable Letter for NDA 21-153, October 3, 2000.	D
NDA: 21-154, Pharmacology/Toxicology Review and Evaluation, October 31, 2000.	E
NDA: 21-154, Clinical and Statistical Review for New Drug Application, December 15, 2000	F

NDA: 21-153, 21-154, Approvable Letters for 21-153, 21-154, December 15, 2000.	G
NDA: 21-153, Memorandum of Director, Division of Gastrointestinal and Coagulation Drug Products, February 20, 2001.	H
NDA: 21-153, 21-154, Approved Labeling, February, 2001.	I

DATED: October 21, 2005

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